

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA

Alexandria Division

MEDYTOX INC.,

Plaintiff,

v.

DAEWOONG CO., LTD. and DAEWOONG
PHARMACEUTICAL CO., LTD.

Defendants.

Case No. 1:21-cv-607 (LMB/IDD)

PLAINTIFF'S RESPONSE TO COURT'S SEPTEMBER 16, 2021, ORDER

Plaintiff Medytox Inc. ("Medytox") respectfully submits this response to the Court's September 16, 2021, Order (DE 27) requesting a status update in light of the fact that the complaint has not been served on defendants Daewoong Co. Ltd. and Daewoong Pharmaceutical Co., Ltd. (together, "Daewoong").

As set forth below, Medytox has entered into settlements with the two companies that are the partners and exclusive distributors of Daewoong's products in the United States, which has the effect of removing the economic justification for proceeding with this suit. Accordingly, Medytox determined that it may be appropriate to seek an order dismissing its complaint without prejudice pursuant to Federal Rule of Civil Procedure 41(a)(2). Before proceeding with such a motion, Medytox had hoped to obtain a ruling on the same type of motion that it has filed in a suit against Daewoong in the United States District Court for the Central District of California, because that ruling might have informed the appropriate course of action in this suit.

In the meantime, to proceed with attempting to serve Daewoong in South Korea pursuant to the Hague Convention would have imposed a cost of tens of thousands of dollars and likely

would not have been completed for several months. Accordingly, Medytox has refrained from pursuing Hague service while it awaits a ruling on its motion to dismiss without prejudice in the C.D. Cal. However, the motion in the C.D. Cal. suit has been scheduled for January 28, 2022, which was the Court's earliest available date. And despite Medytox's having suggested that a hearing is likely not needed on its motion, it has not yet received a response from the Court.

In light of the delay in the C.D. Cal. proceeding, and in response to this Court's inquiry about the status of efforts to serve the complaint on Daewoong, Medytox has determined to proceed with a motion, which is being filed herewith, requesting that the Court dismiss this suit without prejudice pursuant to Rule 41(a)(2).

BACKGROUND

Medytox is a Korean manufacturer of botulinum neurotoxin ("BTX") products. BTX products are biologics that are known for their aesthetic indications (such as the well-known BOTOX® Cosmetic product made by Allergan) and also have therapeutic applications. Daewoong misappropriated Medytox's manufacturing process trade secrets for making BTX products and used them to secure a patent from the U.S. Patent and Trademark Office ("PTO"). U.S. Patent 9,512,418 B2 ("the '418 Patent") claims a method for production of botulinum toxin. As set forth in the complaint, the core inventions claimed in the '418 Patent were conceived and developed by Medytox researchers and belong to Medytox.

The fact that Daewoong misappropriated Medytox's manufacturing process trade secrets and used them to develop the manufacturing process that it claims as its own has already been determined by the U.S. International Trade Commission ("ITC"). Based on the comprehensive record developed in the investigation, including extensive factual and expert discovery and a four-day evidentiary hearing followed by post-hearing briefing, the ITC determined that

Medytox's proprietary manufacturing process trade secrets were misappropriated and used by Daewoong and its partner and exclusive distributor in the U.S. for the sale of Daewoong's BTX products for aesthetic applications, Evolus, Inc. *See In re Certain Botulinum Toxin Products, Processes for Manufacturing or Relating to Same and Certain Products Containing Same*, U.S. ITC Inv. 337-TA-1145 (the "ITC Investigation"). The ITC found that Daewoong and Evolus violated section 337 of the Tariff Act of 1930 (19 U.S.C. § 1337) through the misappropriation of Medytox's manufacturing process trade secrets in the development of Daewoong's BTX products. On that basis, the ITC issued an exclusion order and cease and desist order prohibiting the importation and sale in the United States of Daewoong's BTX products. *Certain Botulinum Toxin Prods., Processes for Mfg. or Relating to Same and Certain Prods. Containing Same*, Inv. No. 337-TA-1145, USITC Pub. 728167, Limited Exclusion Order (Dec. 16, 2020); *Certain Botulinum Toxin Prods., Processes for Mfg. or Relating to Same and Certain Prods. Containing Same*, Inv. No. 337-TA-1145, USITC Pub. 728168, Cease and Desist Order (Dec. 16, 2020).

Medytox subsequently reached a settlement with Evolus that, in exchange for Evolus's agreement to make certain upfront payments and royalties and to convey common stock to Medytox, grants Evolus a license to import and sell the aesthetic BTX products that were at issue in the ITC Investigation. Daewoong is not a party to that settlement and thus is not a "party to the mutual releases of liability, covenants not to sue, or licenses granted to Evolus." *Certain Botulinum Toxin Prods., Processes for Mfg. or Relating to Same and Certain Prods. Containing Same*, Inv. No. 337-TA-1145, USITC Pub. 735885, Joint Pet. of Complainants Medytox and Allergan and Resp't Evolus to Rescind the Limited Exclusion Order and the Cease and Desist Order, Exhibit B at ¶¶ 8.1, 11.1 (Mar. 3, 2021).

On May 14, 2021, Medytox filed this lawsuit to obtain the equitable assignment of Daewoong's ownership rights in the '418 Patent to Medytox based on the fact that Daewoong obtained the '418 Patent by wrongfully taking Medytox's manufacturing process inventions and claiming them as its own. The complaint also sought to correct the errors in inventorship in the '418 Patent – specifically to add Medytox's CEO, Dr. Hyun Ho Jung, and one of its senior researchers, Hack Woo Kim, as inventors.

On the same date, Medytox filed an action in the United States District Court for the Central District of California asserting claims under the Defend Trade Secrets Act (18 U.S. Code § 1836) against Daewoong and its partner and exclusive distributor of Daewoong's BTX products for therapeutic applications in the United States, AEON Biopharma, Inc. ("AEON"). *Medytox Inc. v. Aeon Biopharma, Inc.*, No. 8:21-cv-00903 (C.D. Cal. May 14, 2021).¹

On June 21, Medytox and AEON entered into a settlement under which AEON has issued Medytox 26.68 million shares of common stock, equivalent to 20% of AEON's currently outstanding shares, and has agreed to pay Medytox a royalty on net sales of licensed products over a 15-year royalty period. In exchange, Medytox has granted a license to AEON for its BTX products made by Daewoong. Pursuant to the settlement, Medytox dismissed its claims against AEON in the Central District of California suit with prejudice. Notice of Voluntary Dismissal, ECF No. 18.² Like the settlement agreement with Evolus, Daewoong is not a party to the AEON settlement agreement.

¹ As noted, BTX products have both aesthetic and therapeutic applications. Evolus is Daewoong's U.S. partner and exclusive distributor for aesthetic BTX products, and AEON is Daewoong's U.S. partner and exclusive distributor for therapeutic BTX products.

² Because the settlement with AEON, combined with the settlement with Evolus, means that Medytox has now granted licenses to the exclusive distributors of Daewoong's BTX products in the United States in exchange for substantial equity and royalty payments, Medytox

Because Evolus and AEON hold the exclusive rights to sell the Daewoong BTX products in the United States, the result of Medytox's settlement and license agreements with Evolus and AEON is that the economic justification for proceeding with the current lawsuit is no longer present. As relevant here, Daewoong's BTX products that are imported and sold in the United States would be the likely targets of an infringement claim under the '418 Patent if Medytox were to succeed in obtaining equitable assignment of the patent. These products are now licensed pursuant to Medytox's settlements with Evolus and AEON. While it is theoretically possible that circumstances could change, such that Daewoong or another company would attempt to import and sell the Daewoong BTX products in the U.S., there is no indication at present that such a scenario is likely to occur.

As noted, in light of the impact of the settlements with the two parties that hold the exclusive rights to distribute Daewoong's BTX products in the United States, Medytox filed a motion in the C.D. Cal. suit to dismiss its claims against Daewoong without prejudice pursuant to Rule 41(a)(2). *Medytox Inc. v. Aeon Biopharma, Inc.*, No. 8:21-cv-00903 (C.D. Cal.), Pl.'s Mot. to Dismiss, ECF No. 19. That motion has been scheduled for hearing on January 28, 2022, which was the earliest available date on the Court's schedule. As also noted, Medytox had

agreed not to oppose the dismissal based on mootness of the appeals from the ITC decision, with the understanding that this in turn would lead to vacatur of the ITC's decision. *See* Medytox's Statement of Non-Opposition to Mots. to Dismiss Appeals as Moot, *Allergan Ltd. v. ITC*, No. 21-1653 (Fed. Cir. June 28, 2021). The Federal Circuit has accordingly dismissed the appeals based on mootness and remanded to the ITC. Order, *Allergan Ltd. v. ITC*, No. 21-1653 (Fed. Cir. July 26, 2021). As the ITC has explained, parties can rely on ITC decisions even when they are vacated: "[L]itigants may rely on a vacated Commission opinion not only before a district court, but also before the Commission itself." *In re Certain Air Mattress Sys., Components Thereof, & Methods of Using the Same*, Inv. No. 337-TA-971, Comm'n Op., 2020 WL 861520, at *3 (USITC Feb. 19, 2020) ("*Certain Air Mattress Sys.*"); *see also In re Certain L-Tryptophan, L-Tryptophan Products, & Their Methods of Production*, Inv. No. 337-TA-1005, Comm'n Op., 2020 WL 4500710, at **2-3 (Mar. 5, 2020).

hoped to obtain a ruling on that motion before determining appropriate next steps in this suit.

However, given the apparent timing of the motion in the C.D. Cal. and this Court's inquiry about the status of service of the compliant on Daewoong, Medytox has now determined to proceed with a motion asking the Court to dismiss its claim without prejudice under Rule 41(a)(2) and is submitting that motion together with this Response. As explained in the motion, the reason for requesting a dismissal pursuant to Rule 41(a)(2), rather than withdrawing the suit by notice under Rule 41(a)(1), is to guard against Defendants attempting to count the dismissal toward the two-dismissal limit of Rule 41(a)(1).

If the Court has any further questions concerning this matter, Medytox would be pleased to address them.

Dated: September 29, 2021

Respectfully submitted,

By: /s/ Chad E. Kurtz

Chad E. Kurtz (VSB No. 88863)

Cozen O'Connor

1200 19th Street, NW

Washington D.C. 20036

Telephone: (202) 912-4800

Fax: (202) 861-1905

ckurtz@cozen.com

David H. Herrington (*pro hac vice*)

Arminda B. Bepko (*pro hac vice*)

Cleary Gottlieb Steen & Hamilton LLP

One Liberty Plaza

New York, NY 10006

Telephone: (212) 225-2000

Fax: (212) 225-3999

dherrington@cgsh.com

abepko@cgsh.com

Nowell D. Bamberger (*pro hac vice*)
Cleary Gottlieb Steen & Hamilton LLP
2112 Pennsylvania Avenue, N.W.
Washington, D.C. 20037
Telephone: (202) 974-1500
Fax: (202) 974-1999
nbamberger@cgsh.com

Attorneys for Plaintiff Medytox Inc.

CERTIFICATE OF SERVICE

I, the undersigned, hereby certify that on September 29, 2021, I electronically filed the foregoing with the Clerk of Court using the CM/ECF system, which will send a notification of such filing to all counsel of record, and that I will cause a courtesy copy of this Response to be delivered to counsel that has represented Defendants Daewoong Co., Ltd. and Daewoong Pharmaceutical Co., Ltd. in related proceedings. Additionally, I will cause Defendants to be served with this Response via mail at the following addresses:

Daewoong Co., Ltd.
244 Galmachi-ro Jungwon-gu Seongnam-Si, Korea 13211

Daewoong Co., Ltd.
Bongeunsaro 114-gil 12, Gangnam, Seoul, Korea 06170

Daewoong Pharmaceutical Co.
Bongeunsaro 114-gil 12, Gangnam, Seoul, Korea 06170

By: /s/ Chad E. Kurtz
Chad E. Kurtz (VSB No. 88863)
Cozen O'Connor
1200 19th Street, NW
Washington D.C. 20036
Telephone: (202) 912-4800
Fax: (202) 861-1905
ckurtz@cozen.com